

**JUN - 3 2003**

K021993

Shanchuan Syringe

Shandong Zibo Shanchuan

Medical Instrument Co.,Ltd.

## **510(K) Summary**

### **Submitter Information:**

#### **Name and Address:**

Shandong Zibo Shanchuan Medical Instrument Co.,Ltd.

Jixiang Road, Zichuan, Zibo City, Shandong Province, China 255100

#### **Contact Person:**

Che Xianliang

Director, Shandong Zibo Shanchuan Medical Instrument Co.,Ltd.

Phone Number: 086-533-5750228

Fax Number: 086-533-5750273

### **Device Name:**

Trade Name: SHANCHUAN Syringe

Common Name: Piston Syringe, Hypodermic Needle; Insulin Syringe.

Classification Name: Piston Syringe

### **FDA classification (class I, II, or III)**

Piston syringe 21 C.F.R. 880.5680 Class II

Hypodermic single lumen needle 21 C.F.R. 880.5570 Class II

### **Predicate device**

Terumo Disposable Hypodermic Syringe (K980181);

BD Insulin Syringe (K941657).

### **Intended Use:**

The SHANCHUAN Piston Syringe is design for medical purposes to inject fluids into or withdraw fluids from the body. The syringe has a graduated barrel, a plunger, a hub and a needle.

The SHANCHUAN Insulin Syringe is design for the subcutaneous injection of a desired dose of insulin. The syringe has a graduated barrel, a plunger rod and needle/hub assembly. The needle shield is colored orange.

These devices operate on the principles of a piston syringe. The syringe fluid path is sterile, non-toxic, non-pyrogen and single use, disposable.

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### **Principle of Operation and Technology:**

Each Shanchuan Syringe is designed for manual use therefore it is operated manually.

### **Design and Materials:**

The SHANCHUAN Piston Syringe is consisting of 4 parts: a barrel, a plunger, a gasket and a needle. Barrel, plunger and hub are made from medical polypropylene. The gasket is made from rubber (not include emulsion and natural rubber). The needle is made from  $X_2C_rN_i18-9$ , is stainless steel. The lubricant on barrel and needlepoint is the medical silicon oil, made in Dow Corning Inter-America in USA. Please see Table of Material List

### **Description of Device**

The SHANCHUAN Piston Syringe is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a nozzle for fitting the hub of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.

The Hypodermic Single Lumen Needle is a device intended to inject below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a hub designed syringe or an intravascular administration set.

The Insulin Syringe is a piston syringe, typically sterile, single-use with a needle, used for subcutaneous injection of insulin.

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#### **Substantial Equivalence Comparison I:**

SHANCHUAN Piston Syringe is substantially equivalent to the predicate Terumo Disposable Hypodermic Syringe as follows:

1. Intended Uses: Both SHANCHUAN Piston Syringe and Terumo Disposable Hypodermic Syringe are intended to be used for injecting fluids of withdrawing fluids from the body.
2. Labeling: Both of their labeling for the piston syringe includes the identity of the device (type, size, needle gauge and length) and quantity, they also include the prescription statement according to 801.109(b) (1), except for insulin syringes.
3. Design and materials: The design of SHANCHUAN Piston Syringe and Terumo Disposable Hypodermic Syringe is basically the same. Both devices are comprised of a barrel, plunger, gasket and needle. The materials of them are basically the same. The difference is the gasket and lubricant.
4. Specifications: The physical specifications of SHANCHUAN SYRINGE and Terumo Disposable Hypodermic Syringe are basically the same. The difference between them is syringe sizes and needle length. Both of the Mechanical and Biological are according to the same international standard.
5. Performance:
  - a. Bench: The bench test results demonstrate that the SHANCHUAN Piston Syringe performs equivalent to the predicate devices and is effective when used as intended.
  - b. Clinic: Both of them have been used in clinic for many years, which ensure the effectiveness of the SHANCHUAN Piston Syringe.

#### **Substantial Equivalence Summary:**

In summary, the SHANCHUAN Piston Syringe is substantially equivalent in intended uses, labeling, design and materials, specifications and performance to the predicate Terumo Disposable Hypodermic Syringe (K980181). Any noted differences between the two devices do not raise new issues of the safety and effectiveness. All the results demonstrate that the SHANCHUAN Piston Syringe performs equivalently to the predicate devices and is safe and effective when used as intended.

#### **Substantial Equivalence Comparison II:**

SHANCHUAN Insulin Syringe substantially equivalent to the predicate BD Insulin Syringe as follows:

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1. Intended Uses: Both SHANCHUAN Insulin Syringe and BD Insulin Syringe are intended for the subcutaneous injection of insulin.
2. Labeling: Both of their Labeling for the insulin syringe include the identity of the device (type, needle gauge and length) and quantity. According to 801.403, 'For use with U-100 insulin only 'and graduations should be printed on the barrel of the insulin syringe, please refer to Annex B.
3. Design and materials: The design of SHANCHUAN Insulin Syringe and BD Insulin Syringe is basically the same. Both devices are comprised of a barrel, plunger, gasket and needle. The materials of them are basically the same. The difference is the gasket and lubricant.
4. Specifications: The physical specifications of SHANCHUAN Insulin Syringe and BD Insulin Syringe are basically the same. The differences between them are syringe sizes, needle gauge sizes and needle length. Both of the Mechanical and Biological are according to the same international standard.
5. Performance:
  - a) Bench: The bench test results demonstrate that the SHANCHUAN Insulin Syringe performs equivalently to the predicate devices and is safe and effective when used as intended.
  - b) Clinic: Both of them have been used in clinic for many years, which ensure the safety and effectiveness of the SHANCHUAN Insulin Syringe.

#### **Substantial Equivalence Summary:**

In summary, the SHANCHUAN Insulin Syringe is substantially equivalent in intended use, labeling, design and materials, specifications and performance to the predicate BD Insulin Syringe (K941657). Any noted differences between the two devices do not raise new issues of safety and effectiveness. All the results demonstrate that the SHANCHUAN Piston Syringe performs equivalent to the predicate devices and is safe and effective when used as intended.

#### **Conclusion:**

In summary, the Shanchuan Syringe is substantially equivalent in intended use, labeling, design, materials, specifications and performance to the predicate Terumo Disposable Hypodermic Syringe (K980181) and BD Insulin Syringe (K941657). Any noted differences between them do not raise new issues of safety or effectiveness.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

\*Shangdong Zibo Shanchuan Medical Instruments Company  
C/O Ms. Hairone Che  
12951 Briar Forest Drive, # 303  
Houston, Texas 77077

Re: K021993

Trade/Device Name: Shanchuan Syringe  
Regulation Number: 880.5860, 880.5570  
Regulation Name: Piston Syringe, Hypodermic Single Lumen Needle  
Regulatory Class: II  
Product Code: FMF, FMI  
Dated: March 24, 2003  
Received: March 31, 2003

Dear Ms. Che:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner".

Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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Device Name:

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Indication for Use:

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The syringe fluid path is sterile, non-toxic, non-pyrogen and single use, disposable.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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